

**REMARKS**

Applicants acknowledge receipt of an Office Action dated October 30, 2003. In this response Applicants have amended claims 25 and 33 and have added claims 35-40. Support for these amendments may be found in the specification, *inter alia*, at the paragraph bridging pages 15 and 16. Following entry of these amendments, claims 21-39 are pending in the application.

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

**Claim Objections**

On page 2 of the Office Action, the PTO has objected to claim 25, stating that claim 25 is “of improper dependent form for failing to further limit the subject matter of a previous claim”. In this response, Applicants have amended claim 25 to recite that the composition is “part of a medicament for oral, rectal, transdermal, intrathecal, epi or peridural, or parenteral, namely subcutaneous, intramuscular or intravenous administration.” In view of this amendment, Applicants respectfully request reconsideration and withdrawal of the outstanding objection to claim 25.

**Rejection Under 35 U.S.C. §102**

On page 2 of the Office Action, the PTO has rejected claims 21-32 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent 5,200,198 to Geisslinger *et al.* (hereafter “Geisslinger”). Applicants respectfully traverse this rejection for the reasons set forth below.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). See generally MPEP §2131. Here, Geisslinger fails to disclose “administering a composition...to a human subject suffering from a disease influenced by the inhibition of NF- $\kappa$ B production” as recited in independent claim 21. Accordingly, Geisslinger cannot properly anticipate claim 21 and claims 22-32 which ultimately depend therefrom.

Applicants respectfully request reconsideration and withdrawal of the rejection of claims 21-32 under 35 U.S.C. §102.

### **Rejections Under 35 U.S.C. §103**

On page 3 of the Office Action, the PTO has rejected claims 21-34 under 35 U.S.C. §103(a) as being unpatentable over Geisslinger apparently in view of Berkow *et al.*, The Merck Manual, home edition, 1997 (hereafter “Berkow”). Applicants respectfully traverse this rejection for the following reasons.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 180 USPQ 580 (CCPA 1974). See MPEP §2143.03. Here, neither Geisslinger nor Berkow, taken either individually or in proper combination, teach or fairly suggest “administering a composition...to a human subject suffering from a disease influenced by the inhibition of NF- $\kappa$ B production” as recited in independent claim 21. Accordingly, Applicants submit that the outstanding rejection under §103 is improper and should be withdrawn.

If an independent claim is nonobvious under §103, then any claim depending therefrom is nonobvious. *In re Fine*, 5 USPQ2d 1596 (Fed. Cir. 1988). See MPEP 2143.03. Thus, Applicants submit that claims 22-34, which ultimately depend from independent claim 21, are also non-obvious.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the outstanding rejection under 35 U.S.C. §103.

### **Newly Added Claims**

In this response, Applicants have added claims 35-39. Applicants submit that neither Geisslinger nor Berkow, taken either individually or in combination teach or properly suggest the features of these newly added claims.

With regard to claims 35-38, Applicants submit that neither Geisslinger nor Berkow, taken either individually or in combination teach or properly suggest the claimed doses. These claimed doses are greater than those disclosed in Geisslinger and reflect the fact that the presently claimed invention relates treatment of a distinct population (those suffering from disease influence by the inhibition of NF- $\kappa$ B production) that is treated via a different

mechanism (*i.e.* treatment by the inhibition of NF- $\kappa$ B production which requires greater amounts of the active component) than that disclosed by Geisslinger.

With regard to newly added claim 39, Applicants submit that neither Geisslinger nor Berkow, taken either individually or in proper combination, teach or fairly suggest a step of identifying a human subject suffering from a disease influenced by the inhibition of NF- $\kappa$ B production.

### CONCLUSION

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

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The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.